UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,897	07/31/2001	Masashi Ogawa	Q65704	2025

7590 01/27/2003

SUGHRUE, MION, ZINN,
MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, NW
Washington, DC 20037-3213

EXAMINER	
MORAN, MARJORIE A	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,897	OGAWA ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1,2,4 and 6-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/125,944* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Applicant's election without traverse of Group III, claims 3 and 5, in Paper No. 4 is acknowledged.

Claims 1-2, 4, and 6-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Information Disclosure Statement

The information disclosure statement filed 7/31/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but not all the information referred to therein has been considered.

Although an "International Search Report" and a "European Search Report" are listed on the IDS filed 7/31/01, neither is identified by the application/publication/patent number with which the search report is associated, date of publication or public availability of the search report and/or associated application/publication/patent, author or inventor, etc. No search report was filed with the IDS 0f 7/31/01. The letter accompanying the IDS states that all publications listed therein were filed with a parent application and were listed on an IDS or Form 892 in the parent. The examiner has reviewed parent application 09/125,944 and has not found a properly identified search report listed on an IDS or Form 892 therein. As the Search Reports of the instant IDS

are not identified, and none was filed with the instant IDS, these references have not been considered and have been crossed out to so indicate. The examiner's signature on the IDS indicates that all initialed references have been considered.

It is noted that several references are cited in the specification but have not been supplied in an IDS. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. In addition, the examiner has discovered several US patents and patent applications assigned to the same assignee as that of the instant application which disclose and/or claim similar subject matter to that claimed in the instant application. Applicant is reminded of the duty to properly disclose ALL information known to be material to patentability under 37 CFR 1.56.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 5 are each directed to a method for "measuring protease", however, neither method recites any steps of actually measuring or quantitating a protease. The instant specification, in Examples 12-14, teaches how to measure a protease in a sample by comparing digestion by the sample to digestion by known amounts of protease in a defined period of time; i.e. by comparison to a standard, therefore a method of measuring protease is enabled. However, neither claim 3 nor claim 5 recite any step of comparison to a standard or any other step indicating actual measurement of a protease. In the absence of such a step, it is unclear whether the claims are actually directed to measurement of a protease, or merely to detection of a protease, therefore the claims are indefinite.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,485,926 supported by BAYRAMOGLU et al. (Bioorg. Med. Chem. Lett. (1992), vol. 2 (5), pp. 427-432).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 of '926 is a species of a method wherein instant claim 3 recites the generic method. Specifically, it is noted that instant claim 3 recites open claim language and therefore does not preclude inclusion of a colorant nor a washing step. Further, cross-linkers, as recited in claim 5 of '926, are considered by those in the art to be "hardeners", as supported by the prior art of BAYRAMOGLU (abstract).

Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,485,926 in view of ARAI et al. (US Patent 4,786,595).

Instant claim 5 recites a method of measuring protease by contacting a sample with a thin membrane comprising a layer (a) comprising a substrate, protease inhibitor, and a hardener and a layer (b) comprising a substrate and a hardener, wherein (b) is laminated to (a), detecting traces of digestion on the thin membrane, and comparing digestion on layer (a) with digestion on layer (b).

Claim 5 of '926 discloses a method of measuring protease by contacting a sample with a thin membrane comprising a cross-linker and a substrate, contacting another slice of sample with at thin membrane comprising a cross-linker, substrate, and an inhibitor, detecting digestion on both membranes, and comparing the digestion on the membranes. Claim 5 of '926 does not disclose laminating two layers on one support.

ARAI teaches a multilayer analytical element for measuring protease wherein the element comprises a substrate (Figures 1-4 and col. 17, lines 30-36).

It would have been obvious to one of ordinary skill in the art to have laminated a layer comprising a substrate, hardener (cross-linker), and inhibitor to a layer comprising a substrate, hardener, and inhibitor in a multiplayer analytical element, as taught by ARAI for use in the method of claim 5 of '926 where the motivation would have been to facilitate measurement of protease in a single sample using a single test element, as suggested by the methods in claims 1 and 2 of '926.

Conclusion

Claims 3 and 5 are rejected; all other claims are withdrawn.

The related art made of record and not relied upon which is considered pertinent to applicant's disclosure is NEMORI et al. (US Patent 6,413,734).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703)

305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

January 23, 2003